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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
08/30/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/593,384	LALVANI, AJIT	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18September2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18September2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/4/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Preliminary Amendment, received 18 September 2006, is acknowledged. Claims 3, 5, 6, 7, 8, 9, 11, 12, 13, 15, 17, 20 and 23 have been amended. Claim 14 has been cancelled.

2. Claims 1-13 and 15-23 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Page 2, line 16, "highly specificity" should be "high specificity".

Page 3, line 33, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 13, line 9, what is meant by "is typically has"?

Page 14, lines 2 and 9, "venepuncture" should be "venipuncture".

Page 15, lines 20, 23 and 24, contain an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 16, line 13, reference "Cockle et al" is incomplete.

Page 18, line 20, reference "Cockle et al, 2002" is incomplete.

Page 22, line 16, reference "(18)" is incomplete; line 18, contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Page 23, line 3, "assay.)" should be "assay)."; line 4, contains a beginning parenthesis, i.e., "(With", without a closing parenthesis.

Page 25, line 4, what is "ags/peps"?

Appropriate correction is required.

Sequences

4. M.P.E.P.§2422.03, paragraph 9 recites:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the"Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

Page 17, lines 8, 9, 10, 11, 12, 23, 29 and 32 contain sequences without the required SEQ ID NO.

Page 22, lines 5, 6, 7, 8, 11, 12, 13, and 14 contain sequences without the required SEQ ID NO.

Page 29, lines 2, 3, 5, and 6 contain sequences without the required SEQ ID NO.

Drawings

5. Figure 1A is objected to because all of the bars appear to be solid and therefore do not distinguish between TB and unexposed patients.

6. Figure 3 is objected to because the figure does not comply with M.P.E.P. §2422.02, third paragraph, which recites that "the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Appropriate correction is required.

7. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that one or more peptides are "represented by" SEQ ID NO's 2 to 18. The specification does not define the metes and bounds of "represented by".

9. Claims 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of ascertaining the stage of an *M. tuberculosis* infection in a human by determining whether there is a differential T cell response to different antigens in the human.

The instant specification only utilizes antigens from *M. tuberculosis* for such determinations. The specification does not show that any/all antigens from any/all other sources, e.g., cancer, fungal infections, or viral infections, can fulfill the scope of the claims. Thus, the claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. Claims 1-13 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to methods or kits for diagnosing *M. tuberculosis* infection or exposure utilizing peptides "having or comprising" sequences SEQ ID NO:1 to SEQ ID NO:18 and determining whether any T-cells recognize said peptides.

The use of the open language terms, i.e., having or comprising, permits any number of amino acids on either end of the know SEQ ID NO sequences. These unknown regions have no restriction as being *M. tuberculosis* recognizable sequences.

Therefore, it unclear how one differentiates between T-cells which are recognizing the known sequences from T-cells which are recognizing the unknown regions which may have no relationship with infection or exposure to *M. tuberculosis*.

11. Claims 1-13 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to sequences "shown in" a specific SEQ ID NO. It is unclear what are the metes and bounds of "shown in". Does it mean only the whole SEQ ID NO or a subsequence of the SEQ ID NO? If it is the whole SEQ ID NO., then it is recommended that the language be, e.g., "the sequence SEQ ID NO:1".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 8-13, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Agger et al (WO01/79274, 25 October 2001).

Claim 15 is drawn to a composition requiring only one listed moiety, i.e., a peptide as defined in claim 1. At least one embodiment of claim 1 is a peptide having sequence SEQ ID NO:1.

Agger et al teach a sequence SEQ ID NO:22 (Rv3879c) which is identical to instant SEQ ID NO:1 (pages 22-23 of Sequence listing) and compositions comprising said sequence (claims 9-11).

Claim 16 is drawn to a composition according to claim 15 wherein said one or more further T-cell antigens are selected from ESAT-6, CFP1o, Rv3873, Rv3878 or Rv1989c.

Agger et al teach a sequence SEQ ID NO:22 which is identical to instant SEQ ID NO:1 (pages 22-23 of Sequence listing) and compositions comprising said sequence (claims 9-11) with one other sequence, Rv3878 (claims 9-11).

Claim 1 is a method of diagnosing *M. tuberculosis* in a human by contacting T-cells from said human with one or more peptides of which SEQ ID NO:1 is one of the peptides.

Agger et al teach skin testing (T-cell mediated DTH), T-cell proliferation assays, and cytokine (IFN-γ) release assays utilizing peptides for diagnosing *M. tuberculosis* infection (Example 2) and teach that Rv3879c may be utilized in said assays (pages 7-9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aggers et al ((WO01/79274, 25 October 2001).

One embodiment of claim 17 is a kit comprising a peptide SEQ ID NO:1. The recitation of "optionally a means for detecting recognition of a peptide by T-cells" places no further restriction on this embodiment because such a means is not required. Thus, the only requirement for this embodiment is a kit comprising peptide SEQ ID NO:1.

Claims 18-20 likewise do not require said means.

Agger et al teach a sequence SEQ ID NO:22 (Rv3879c) which is identical to instant SEQ ID NO:1 (pages 22-23 of Sequence listing) and compositions comprising said sequence (claims 9-11). However, Agger et al do not teach "kits" comprising said peptide.

Agger et al teach skin testing (T-cell mediated DTH), T-cell proliferation assays, and cytokine (IFN-γ) release assays utilizing peptides and antibodies for diagnosing *M. tuberculosis* infection (Example 2) and teach that Rv3879c (SEQ ID NO:22) may be utilized in said assays (pages 7-9).

Therefore, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to place all of the reagents of the methods taught by Agger et al into a convenient kit to facilitate the assays.

Conclusion

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Larry Helms, at (571)272-0832.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 25, 2010